



Application No. 10/633,349

Amendment dated May 9, 2005

RESPONSE TO OFFICE ACTION dated January 11, 2005

### **REMARKS / ARGUMENTS**

The action by the Examiner in this application, together with the references cited, has been given careful consideration. Following such consideration, claims 1-7, 12, 16 and 17 have been amended, claims 14 and 15 have been canceled, claims 21-24 have been added, and claims 8-11, 13 and 18-20 remain unchanged. It is respectfully requested that the Examiner reconsider the claims in their present form, together with the following comments, and allow the application.

As the Examiner well knows, the present invention relates to a container for holding medical instruments to be microbially decontaminated in a reprocessor. The container includes a tray and a lid. The tray includes a fluid inlet and a fluid outlet. Each inlet includes a flexible, movable valve element that is movable by a mechanical actuator on the reprocessor from a normally closed position to an open position. Movement of the flexible valve element occurs when the container is inserted into the reprocessor as the flexible valve element comes into engagement with the mechanical actuator on the reprocessor.

In a preferred embodiment, the container includes a second fluid inlet port. One of the fluid inlet ports is connected to nozzle means within the container that are operable to spray fluids circulating through the reprocessor onto medical instruments within the container. Another one of the fluid inlets is connectable to connection means that in turn are connectable to medical instruments that are to be decontaminated within the container so as to force fluid through the medical instruments. The fluid outlet represents a drain for draining fluid circulated through the container.

In response to the Examiner's rejections, the claims have been amended to define more clearly the patentable invention Applicants believe is disclosed herein. More specifically, claim 1 has been amended to indicate that the container includes a fluid inlet and a fluid outlet. The fluid inlet and the fluid outlet each have a flexible valve element "that is movable by a mechanical actuator on said reprocessor" between an open position and closed position.

Claim 7 has been amended to indicate that said container includes a fluid inlet passage and a fluid outlet passage and that each of said passages includes a valve assembly having a valve element that is "movable through contact with an actuator on said reprocessor." Claim 7 has further been amended to indicate that the valve element is "movable to said open position when said container is placed within said reprocessor and moving to said closed position when said container is removed from said reprocessor."

Claim 12 has been amended to indicate that the container has a fluid inlet and a fluid outlet, and that each has a "flexible valve element that is movable between an open and a closed position." The claim has further been amended to indicate that an actuator in the deactivation chamber is "associated with each valve element" to move said valve element between the open and closed position.

New claims 21-24 have been added to indicate that the container has a second fluid inlet that also includes a flexible valve element that is movable through contact with the mechanical actuator on the reprocessor. Claim 22 defines that one of the fluid inlets in the container is in fluid communication with a nozzle within the container. New claim 23 indicates that one of the fluid inlets in the container is in fluid communication with fluid connectors that are connectable

with medical instruments within the container. New claim 24 indicates that one of the fluid inlets is in fluid communication with a seal defined between the tray and the lid.

It is respectfully submitted that none of the cited references, alone or together, teaches, suggests or shows the claims in their present form.

Claims 1-5 and 7-11 stand rejected under 35 U.S.C. Section 102(b) as being anticipated by U.S. Patent No. 5,534,221 to Hillebrenner et al. The '221 patent discloses a cassette for use in a system for sterilizing objects that may be placed in the cassette. The '221 patent specifically relates to a sterilizing agent in the form of a sterilizing gas (column 5, line 52), wherein a vacuum is drawn on the outlet port side of the cassette to draw the sterilizing gas through the cassette and through the lumens of the object within the cassette. Accordingly, the '221 patent teaches a vacuum system for drawing a sterilizing gas through the cassette. The '221 patent indicates that the inlet port and the outlet port of the cassette have "well-known check valves" so that when connections are made to the inlet port and the outlet port, the sterilizing gas can flow through the inlet port into the cassette, around and through medical instruments within the cassette and out through the outlet port (column 6, lines 30-35).

As set forth in the disclosure of the '221 patent, the check valves within the inlet and outlet ports operate based upon a pressure differential when a vacuum is drawn on the outlet port. In this respect, the '221 patent does not teach, suggest or show fluid inlets and outlets having a flexible valve element that is movable by a mechanical actuator on the reprocessor, as currently set forth in claims 1 and 7. Still further, the '221 patent does not teach, suggest or show a mechanical actuator associated with each valve element for activating the valve element when the container is placed within the reprocessor. In the '221 patent, the check valves within

the inlet and outlet ports operate only during the sterilization cycle, and do not open when the cassette is placed within the reprocessor as presently set forth in the claims.

For the foregoing reasons, it is respectfully submitted that the claims in their present form are not anticipated by the '221 patent.

Claims 12-20 stand rejected under 35 U.S.C. Section 103(a) as being unpatentable over the '221 patent to Hillebrenner et al. in view of U.S. Patent No. 5,217,698 to Siegal et al.

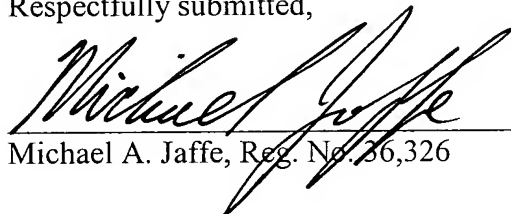
The '698 patent discloses a sterilization system having a sterilization chamber with an access opening for receiving a cassette. The '698 patent discloses a cassette having openings therein to allow fluid to circulate therethrough. The fluid must flow through a tortuous path between the inlet port and the outlet port to flow through the cassette. The Examiner takes the position that it would be obvious to use the cassette of the '221 patent in the sterilization system of the '698 patent. However, as indicated above, the '221 patent discloses a cassette that is operable in a vacuum system for conveying a gaseous sterilant through the cassette. It is respectfully submitted that such a cassette as disclosed in the '221 patent would not find advantageous application in a sterilization system wherein a fluid is directed through a cassette. Even then, such a system would not teach, suggest or show a cassette wherein the fluid inlet and the fluid outlet are maintained in an open position once the container is placed within the reprocessor, as presently set forth in the claims. In this respect, since the valve elements of the claimed container are in an open position once the container is placed in the reprocessor, fluid flowing into or out of the container is not required to overcome a biasing pressure (i.e., the check valves of the '221 patent) for such fluid to pass through the container or medical instruments therein.

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For the foregoing reasons, Applicants respectfully submit that the combination of the '221 patent and the '698 patent do not teach, suggest or show the system set forth in claims 12-20, wherein each valve element in the container is associated with an actuator in the decontamination chamber of the system such that the actuator opens the valve elements once the container is disposed in the deactivation chamber.

For the foregoing reasons, it is respectfully submitted that the claims in their present form are distinguishable from the cited references, and favorable action is therefore respectfully requested.

Respectfully submitted,



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I hereby certify that this correspondence (along with any paper referenced as being attached or enclosed) is being deposited on the below date with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: May 9, 2005



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